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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,569	06/25/2001	Maurice M. Moloney	9369-183	8071

7590 08/12/2003

Micheline Gravelle
Bereskin & Parr
40 King Street West
Box 401
Toronto, ON M5H 3Y2
CANADA

EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
1638	13

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/887,569

Applicant(s)

MOLONEY ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 18, 20 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) 26-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 18, 20 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' amendment of 14 May 2003 has overcome the rejection under 35 USC 112, second paragraph.

Claims 17, 20 and 24 remain rejected under 35 U.S.C. 102(b) as being anticipated by EP 241,963 (LEDOUX), as stated in the last Office action.

Claims 17-18, 20 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/13993 (UPJOHN), as stated in the last Office action.

Claims 17-18, 20 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/13993 (UPJOHN) in view of Vandekerckhove et al, as stated in the last Office action.

No claim is allowed.

Applicants' arguments filed 14 May 2003, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicants urge that the rejection over LEDOUX is improper, given the failure of the reference to enable whole plants grown from the transformed seeds, which plants would stably maintain the plasmid containing the growth hormone-encoding gene introduced into the initially transformed seeds. The Examiner maintains that the claims are not drawn to whole plants grown from transformed seeds. Instead, the claims are drawn to seeds which contain somatotropin, i.e. growth hormone. Even the transient expression of the plasmids in the seeds, immediately following their introduction into the

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seeds, would result in the production of somatotropin, i.e. seeds containing recombinantly expressed somatotropin as claimed.

Applicants urge that the claims are not anticipated by UPJOHN, since the reference does not teach fusion proteins comprising a portion of the mature seed storage protein. The Examiner maintains that the claims do not recite a fusion protein comprising a portion of a mature seed storage protein. The claims merely recite seeds containing somatotropin (claims 17, 20 and 24), or seeds comprising a fusion protein comprising somatotropin. Somatotropin ligated to a proteinaceous signal sequence from a non-somatotropin gene constitutes a fusion protein. Applicants' arguments are moot regarding claims 17, 20 and 24.

Applicants urge that the obviousness rejection is improper, given the lack of motivation to combine the references and the lack of reasonable expectation of success, as evidenced by Bosch et al. The Examiner maintains that the motivation to combine can be found in the teachings of the references, as cited in the last Office action.

Regarding Bosch et al, the reference teaches that the somatotropin coding sequence, ligated to a sequence encoding a signal sequence from a plant pathogenesis-related protein, was in fact expressed in seeds, but that the particular signal sequence could not prevent degradation of the protein product. Bosch et al teach that a signal sequence which targets the protein "to a compartment where proteins are stably accumulated" should be employed (see, e.g., page 309, column 1, top paragraph). Thus, Bosch et al reinforce the reasonable expectation of success

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when using the signal sequence from seed storage protein genes as taught by the prior art.

Furthermore, Applicants' evidence of unexpected results depends upon the use of a single type of fusion protein, namely a fusion of an oil body protein with somatotropin. In contrast, the claims are broadly drawn to any type of protein fused to somatotropin. See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

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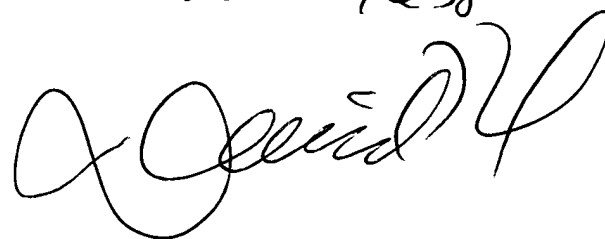
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 9, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.